IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	Civil Action No. 05-356-KAJ (consolidated)
	)	**REDACTED PUBLIC VERSION**

PLAINTIFFS' OPENING BRIEF ON CLAIM CONSTRUCTION

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I. INTRODUCTION

Janssen Pharmaceutica, N.V., Janssen, L.P., and Synaptech, Inc. (collectively, "Plaintiffs") seek to prevent Barr Laboratories, Inc., Barr Pharmaceuticals, Inc., and Alphapharm, Pty. (collectively, "Defendants")[1] from infringing Plaintiffs' patent, U.S. Patent No. 4,663,318 ("the '318 Patent"), attached as Exhibit A. The '318 Patent claims the use of galantamine hydrobromide,[2] marketed by Plaintiffs under the trademark RAZADYNE®, in the treatment of Alzheimer's disease.[3] After Defendants filed Abbreviated New Drug Applications ("ANDAs") with the U.S. Food and Drug Administration ("FDA") to market generic versions of RAZADYNE, which included certifications that the '318 Patent is invalid, Plaintiffs brought this

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[1] As the Court is aware, the present lawsuit is a consolidated action in which a total of seven defendants (Alphapharm Pty Ltd.; Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.; Dr. Reddy Laboratories Inc. and Dr. Reddy Laboratories Ltd.; Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc.; Par Pharmaceutical, Inc. and Par Pharmaceuticals Companies, Inc.; Purepac Pharmaceutical Co. and Alpharma, Inc; and Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.) filed ANDAs to make generic copies of Plaintiffs' RAZADYNE® product. During the course of discovery, the Dr. Reddy's, Mylan, Purepac, and Teva defendants all elected to enter into a stay of the proceedings against them and be bound by the judgment in the case against the remaining defendants. *See* 5/30/06 Stipulation and Order (DRL) (D.I. 236); 5/31/06 Stipulation and Order Granted by Judge Kent A. Jordan (DRL) (Dkt. Line Item); 6/16/06 Stipulation and Order (Mylan) (D.I. 258); 6/19/06 Stipulation and Order Granted by Judge Kent A. Jordan (Mylan) (Dkt. Line Item); 4/20/06 Stipulation and Order (Purepac) (D.I. 177); 5/5/06 Stipulation and Order Granted by Judge Kent A. Jordan (Purepac) (Dkt. Line Item); 7/19/06 Stipulation and Order (Teva) (D.I. 298); 7/20/06 Stipulation and Order Granted by Judge Kent A. Jordan (Teva) (Dkt. Line Item). Defendant Par elected instead to withdraw its Paragraph IV Certification contesting infringement and validity and substitute in its place a Paragraph III Certification that it will not seek to market its generic copy of RAZADYNE® until the '318 Patent expires in December 2008. *See* 4/18/06 Stipulation of Dismissal Without Prejudice as to Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (Par) (D.I. 174); 5/5/06 Stipulation of Dismissal Without Prejudice as to Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. Granted by Judge Kent A. Jordan (Par) (D.I. 186).

[2] Galantamine hydrobromide is a pharmaceutically-acceptable, acid-addition salt of galantamine. *See* '318 Patent at 1:56-59. In the technical literature, Galantamine is sometimes spelled galanthamine.

[3] RAZADYNE® is a registered trademark. However, for purposes of this motion, Plaintiffs will refer to the RAZADYNE product without using the trademark symbol.

suit. Defendants concede that the filing of their ANDAs infringe both asserted Claims 1 and 4 (*see* 12/2/05 Stipulation Not to Contest Infringement (D.I. 49)), and the only remaining issues relate to Defendants' invalidity defenses. The issue of alleged invalidity is informed by the interpretation of a small number of claim terms of the '318 Patent. This brief sets forth the Plaintiffs' reasoning supporting their proposed claim construction.

Plaintiffs ask that the Court interpret various claim terms found in Claim 1 of the '318 Patent in accordance with their plain and ordinary meaning, as set forth in Plaintiffs' portion of the Joint Claim Construction Chart ("JCCC"), submitted herewith. The patent specification and prosecution history are consistent with such interpretation, as are the opinions of the Plaintiffs' and Defendants' experts in this case.

II. BACKGROUND

A. Alzheimer's Disease

For centuries, "senility," or diminished mental capacity and loss of memory with aging, was thought to be a normal part of the aging process. *See* Ex. B, Opening Expert Report of Dr. Howard M. Fillet (hereinafter "Fillet Report at __") at ¶ 27. Alzheimer's was first described as a distinct disease in 1907 by the German researcher Alois Alzheimer, who examined the brain tissue of a woman who had died in her 50s of a dementing illness and recorded the plaques and tangles that mark the disease that came to bear his name. At that time and for decades thereafter, Alzheimer's disease was believed to be a rare disease in middle aged patients and did not encompass senile memory loss and dementia occurring in the elderly.

By the late 1960s, science recognized that the plaques and tangles observed by Alzheimer in presenile dementia also appeared in senile elderly patients. As a result, senile dementia too was recognized as a disease, with the senile form of Alzheimer's disease referred to as "senile dementia of the Alzheimer's type." Ex. B, Fillit Report at ¶¶ 28-30 (citing Blessed, G.

et al., "The Association Between Quantitative Measures of Dementia and of Senile Change in the Cerebral Grey Matter of Elderly Subjects," *British Journal of Psychiatry* 114:797-811 (1968)). Today, many scientists view the presenile and senile forms of the disease as essentially the same, and refer to both as Alzheimer's disease. In the elderly, Alzheimer's is far from rare – it is recognized as an epidemic that strikes almost half of us who live into our mid-80s. *See* Ex. C, Opening Expert Report of Dr. Jeffrey L. Cummings (hereinafter "Cummings Report at ¶__") at ¶¶ 61-70; Ex. D, Opening Report of Dr. Joseph T. Coyle (hereinafter "Coyle Report at ¶__") at ¶ 30.

It has long been known that Alzheimer's brain tissue is characterized by two particular pathologic features: "plaques" and "tangles." Ex. C, Cummings Report at ¶ 32. At the time of the filing of the '318 Patent, the existence of these markers of Alzheimer's disease was known, but their role in the disease was uncertain. *Id.* at ¶ 35. What was recognized was the symptomatic hallmark of Alzheimer's disease – the devastating decline in cognitive function. While many other symptoms are common in patients suffering from Alzheimer's disease (e.g., depression, anxiety, aggressive behavior, and apathy), a decline in cognitive function is the core feature of the disease.

B. Dr. Davis's Invention: Galantamine as a Treatment for Alzheimer's Disease

By the time of the filing of the '318 Patent, research had been conducted on a wide range of possible therapies for Alzheimer's disease, but there were still no effective treatments available, especially for the cognitive decline at the center of the disease. *Id.* at ¶¶ 67-68, 84.

In the late 1970s and early 1980s, Dr. Bonnie Davis was a medical doctor, studying the so-called "neuroendocrine window," the way in which hormones in the blood can shed light on what is going on in the brain. Using this novel approach to the problem, she came

to understand the promise that galantamine offered, and invented a method for treating Alzheimer's disease using galantamine or its acid addition salts. She applied for a patent in January of 1986.

The '318 Patent was issued by the United States Patent and Trademark Office ("PTO") on May 5, 1987 to its inventor, Dr. Bonnie M. Davis, and it expires on December 14, 2008. It was exclusively licensed to Janssen Pharmaceutica N.V. on November 30, 1995. Janssen holds an approved new drug application ("NDA") – approved by the FDA in 2001 – for galantamine hydrobromide tablets used in the treatment of mild to moderate Alzheimer's disease and currently markets the tablets under the name "RAZADYNE" (formerly called "REMINYL").

III. ARGUMENT

A. The Law of Claim Construction

Claim construction is an issue of law to be resolved by the Court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). Claim construction begins with the language of the claims themselves. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005); *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Claim terms are to be given their ordinary and customary meaning. *Phillips*, 415 F.3d at 1312; *Vitronics*, 90 F.3d at 1582. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1313.

To determine the ordinary and customary meaning of claim terms, the Court looks to the written description and the prosecution history, which are deemed to be have been read by

the person of ordinary skill in the art in their efforts to understand the meaning of the claims. *Id.*; *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998); *V-Formation, Inc. v. Benetton Group SPA*, 401 F.3d 1307, 1310 (Fed. Cir. 2005) (the written description and the prosecution history provide "the technological and temporal context to enable the court to ascertain the meaning of the claim to one of ordinary skill in the art at the time of the invention"). "[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the *single best guide* to the meaning of a disputed term." *Vitronics*, at 1582 (emphasis added); *see also Phillips*, 415 F.3d at 1315, 1321.

Extrinsic evidence, including expert and inventor testimony, dictionaries and learned treatises, may be useful in the art of claim construction; however, it is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language'" *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) *quoting Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n*, 366 F.3d 1311, 1318 (Fed. Cir. 2004); *see also Phillips*, 415 F.3d at 1317. "[I]f the meaning of the claim limitation is apparent from the intrinsic evidence alone, it is improper to rely on extrinsic evidence other than that used to ascertain the ordinary meaning of the claim limitation." *Bell Atlantic Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1268-69 (Fed. Cir. 2001).

Similarly, if after applying all the available tools of claim construction a claim term remains ambiguous, it is appropriate to construe the terms so as to preserve their validity. *See Phillips*, 415 F.3d at 1327; *see also Liebel-Flarsheim Co. v. Medrad, Inc*, 358 F.3d 898, 911 (Fed. Cir. 2004); *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1557 (Fed. Cir. 1996); *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996) (adopting the narrower construction on the basis that to do otherwise "would undermine the fair

notice function of the requirement that the patentee distinctly claim the subject matter disclosed in the patent from which he can exclude others temporarily"); *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1581 (Fed. Cir. 1996) ("to the extent that the claim is ambiguous, a narrow reading which excludes the ambiguously covered subject matter must be adopted."); *Digital Biometerics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998) ("Because the applicant has the burden to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention,' 35 U.S.C. § 112, ¶ 2 (1994), if the claim is susceptible to a broader and narrower meaning, and the narrower one is clearly supported by the intrinsic evidence while the broader one raises questions of enablement under § 112, ¶ 1, we will adopt the narrower of the two."). Consequently, when the proposed claim construction is based on sound claim construction principles, it is reasonable to infer that the PTO would not have issued an invalid patent. *Phillips*, 415 F.3d at 1327.

B. Disputed Claim Terms

All of the disputed claim terms are located in Claim 1 of the '318 Patent. Claim 1 of the '318 Patent[4] describes the invention of treating Alzheimer's disease using galantamine and reads as follows:

> A method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof.
>
> Ex. A, '318 Patent at 3: 6-10.

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[4] Claim 4 depends from Claim 1 and specifies a dosage range for oral administration. Specifically, Claim 4 states: "A method according to claim 1, wherein said administration is oral and in the range 10-2000 mg per day." Because there are no disputed terms in Claim 4 of the '318 Patent (separate from those in Claim 1 from which Claim 4 depends), it need not be considered separately.

As seen in the JCCC, the Plaintiffs and the Defendants have identified various claim terms which each believes requires construction by this Court. Both Plaintiffs and Defendants concur that the Court needs to define "a method of treating," "Alzheimer's disease and related dementias," and "a therapeutically effective amount." In addition, Defendants also seek to have the Court construe "a patient" – a term that Plaintiffs do not believe, for reasons explained below, has fairly been placed at issue.

Notwithstanding this complication, at bottom, there are only four disputed claim terms, each appearing in Claim 1 of the '318 Patent: (1) "Alzheimer's disease and related dementias," (2) "a patient suffering from such a disease," (3) "a therapeutically effective amount," and (4) "[a] method of treating." While the order of these terms in this brief differs from their sequence in the language of Claim 1, because the constructions of terms (2) through (4) each stem from an understanding of term (1) "Alzheimer's disease and related dementias," Plaintiffs' proposed claim constructions and the support for these claim constructions is presented in that order *seriatim*.

1. "Alzheimer's disease and related dementias"

As used in the '318 Patent, "Alzheimer's disease and related dementias" refers to presenile dementia and senile dementia of the Alzheimer's type.[5] The specification expressly refers to Alzheimer's disease as the presenile form of the disease. Ex. A, '318 Patent at 1:34-36 ("Alzheimer's disease, presenile dementia, causes much distress not only to those suffering form the disease, but also those who are close to them.") In that context, "Alzheimer's disease and

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[5] Although the term "Alzheimer's disease and related dementias" appears in the claim preamble, it serves as an antecedent basis for the claim term "a patient suffering from such disease" (discussed below) and thus serves to limit the claim. *Rapoport v. Dement*, 254 F.3d 1053, 1059 (Fed. Cir. 2001) (preamble found to be a limitation because the preamble is necessary to give "a proper antecedent basis" to a term used in the body of the claim).

related dementias" encompasses both the presenile form and the senile form of the disease – senile dementia of the Alzheimer's type.

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The file history – including art cited therein – confirms this view. For example, during prosecution, Dr. Davis directed the examiner's attention to a July 1986 article by Hershenson and Moos, "Drug Development for Senile Cognitive Decline," Journal of Medicinal Chemistry, 29(7):1125-1130 (hereinafter "the Hershenson article," attached as Ex. F) as describing the problem that the invention was intended to solve, namely that "Alzheimer's disease is a major and growing problem in our society." *See* September 9, 1986 Amendment Responsive to Office Action of April 10, 1986 (hereinafter "9/9/86 Response") at 2, attached as Exhibit G. In describing Alzheimer's disease, the Hershenson article states: "Currently several dementias can be treated … but others cannot, most notably primary degenerative dementia (PDD; also called senile dementia, senile dementia of the Alzheimer's type, Alzheimer's disease, organic brain syndrome)." Ex. F, Hershenson article at 1125. The Hershenson article explains that Alzheimer's disease was the name given for the disease, witnessed by Alois Alzheimer, in a 56-year-old woman characterized by "personality changes, disorientation, and memory loss." *Id.* These symptoms were determined to result from the presence of neuritic plagues and neurofibriallotry tangles found during a postmortem microscopic examination of the woman's brain tissue. *Id.* "The microscopic changes had previously been observed only in the brains of

people over 70 years of age...." *Id.* The Hershenson article notes that "whether PDD is a single entity or two disorders; one with an onset before age 65 (presenile dementia), and a second with symptoms appearing in later life (senile dementia) ... has not been resolved." *Id.* at 1126. The Hershenson article thus makes clear that senile dementia of the Alzheimer's type is a dementia related to the original presenile form of Alzheimer's disease and hence confirms that "Alzheimer's disease and related dementias" as used in the '318 patent means both presenile and senile dementia of the Alzheimer's type.

Defendants do not appear to dispute that "Alzheimer's disease and related dementias" encompasses both presenile dementia and senile dementia of the Alzheimer's type. *See* JCCC at 1; . However, Defendants appear to propose that the claim term be construed to encompass other, purportedly "related" dementias, which they fail to identify.

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Moreover, Defendants' proposed construction is unsupported by the intrinsic evidence, which speaks only to dementias of the Alzheimer's type. Defendants' proposed construction, which simply parrots the language of the claim, does not serve the ends of claim construction and, to the degree it has any meaning outside the construction proposed by Plaintiffs, is unfaithful to the scope of the invention described in the patent and the file history. It should therefore be rejected.

2. *"a patient suffering from such a disease"*

Defendants propose to construe the term "patient" in the claims to mean "mammals, including humans." JCCC at 2. Defendants' construction, however, improperly ignores the context of the claim, however, which refers to "a patient suffering from such a disease" – that is, a "patient" suffering from Alzheimer's disease or related dementias. *See, e.g,*

Pause Tech., LLC v. TiVo, Inc., 419 F.3d 1326, 1331 (Fed. Cir. 2005) (claim language should be construed in the "context" of the whole claim). Tellingly, Defendants fail to identify what mammals suffer from dementia of the Alzheimer's type. This failure is unsurprising:

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Hence, in the context of the claim, the term "patient" logically means humans and should be construed that way. But it is unnecessary to even reach the question. Because Defendants have not identified what mammals other than humans suffer from Alzheimer's type dementias, and because their experts do not opine on any claim scope outside of humans, the claim term simply has not fairly been placed at issue in this case.

3. *"therapeutically effective amount"*

The term "therapeutically effective amount" is a claim term common to many pharmaceutical patent claims, generally understood (and construed by the Court of Appeals for the Federal Circuit) to mean an amount sufficient to cause a therapeutic benefit. *See, e.g. Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1301 (Fed. Cir. 2004), (affirming the interpretation of the term "therapeutically effective amount" to mean "an amount sufficient to have therapeutic benefit"). The interpretation of this claim term must be in the context of the '318 Patent and what Dr. Davis's invention intended to achieve. The specification and claims of the '318 Patent make clear that a therapeutically effective amount of galantamine is intended as a treatment for Alzheimer's disease – and, particularly, as a treatment for the cognitive decline at the center of the disease. For example, the patent specification states that "an object of the present invention [is] to improve the cognitive function of patients with Alzheimer's disease," and that this is accomplished by administering "an effective Alzheimer's disease cognitively-enhancing amount of galantamine." Ex. A, '318 Patent at 1:41-42, 1:46-47. Hence, Plaintiffs

have defined "therapeutically effective amount" to mean "an amount sufficient to cause a therapeutically beneficial effect on symptoms of Alzheimer's disease and related dementias."

By contrast, Defendants suggest that this term should be defined as "an amount sufficient to produce the desired therapeutic change or effect in a patient." It is unclear whether Defendants' construction differs from Plaintiffs', since Defendants do not identify the "desired" therapeutic change or effect. However, claim terms must be construed in context, and hence the therapeutically beneficial effect both parties agree is encompassed within the term "therapeutically effective amount" should be defined, and clearly refers to the therapeutic benefits implied by a method of treating Alzheimer's disease. Hence, Plaintiffs' proposed construction, which incorporates the context of the claim term in its construction, should be adopted. In the next section, we take up the meaning inherent in a method of treating the disease.

4. *"method of treating"*

Both Plaintiffs and Defendants agree that the claim term, "method of treating" should be construed as an additional guide to the scope of the claim. Plaintiffs propose that the term be construed to mean "a method of alleviating the symptoms or deferring the decline associated with Alzheimer's disease, including the cognitive impairment that is the core symptom of the disease, in a manner beneficial to the patient – that is, in a manner that is safe, tolerable, and produces clinically meaningful results."

The claim context is, of course, a method of treating Alzheimer's disease and related dementias. The intrinsic evidence spells out this context and makes clear that a "method of treating" is integrally linked with alleviating or otherwise addressing the cognitive decline of Alzheimer's disease. As noted in the previous section, the specification expressly refers to the use of galantamine to enhance the cognition of Alzheimer's patients: "It is an object of the

present invention to improve the cognitive function of patients with Alzheimer's disease." (Ex. A, '318 Patent at 1:41-42); "A method for treating Alzheimer's disease and related dementias which comprises administering to mammals, including humans, an effective Alzheimer's disease cognitively-enhancing amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof." (Ex. A, '318 Patent at 1:45-50). The specification thus makes clear that the claimed treatment of Alzheimer's disease includes alleviation of the patient's cognitive decline in a therapeutic way.

That the claimed "method of treating" Alzheimer's disease also be safe and tolerable is shown by the claim language and the intrinsic evidence. Safety and tolerability is inherent in the concept of treatment and implied, as well, by the restriction in the claim to "pharmaceutically acceptable" salts of galantamine. A treatment that is not safe and tolerable cannot be administered to a patient in a therapeutically effective way. In addition, the patent specification describes the possibility that dose titration may be necessary (*id.* at 1:64-66) – a well-established way of improving the safety and tolerability of drug therapy.

Defendants' proposed construction suffers from two shortcomings. First, it omits the element of treating the cognitive decline of Alzheimer's disease. Instead, Defendants posit that this term can mean a "method for improving the cognitive or functional status of a patient with Alzheimer's disease or related dementias." JCCC at 2 (emphasis added). But Defendants have not indicated what they mean by an improvement in "functional status," let alone what would constitute an "improvement" in that status. It does not serve the function of claim construction. Second, Defendants' construction also omits the concept of treatment – that is, that the claimed "improvement" be therapeutically meaningful – that is, safe, tolerable, and of clinical benefit to the patient.

* * *

Plaintiffs' proposed constructions of the disputed claim terms of the '318 Patent are consistent with the language of the claims, the written description, and the file history. Were the Court to adopt Defendants' constructions, Dr. Davis's invention could be argued to extend to the administration of galantamine to an unknown animal suffering from an unspecified form of dementia so as to improve the animal's "function" in an undetermined way. Where, as here, the narrower claim construction finds ample support in the intrinsic evidence, any twinge of remaining ambiguity should be resolved in favor of Plaintiffs' proposed definitions in accordance with the maxims set forth in *Liebel-Flarsheim, Modine Manufacturing, Athletic Alternatives, Ethicon Endo-Surgery,* and *Digital Biometerics*, cited above.

IV. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court adopt Plaintiffs' proposed constructions of the disputed claim terms of the '318 Patent set forth in their portion of the JCCC.

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